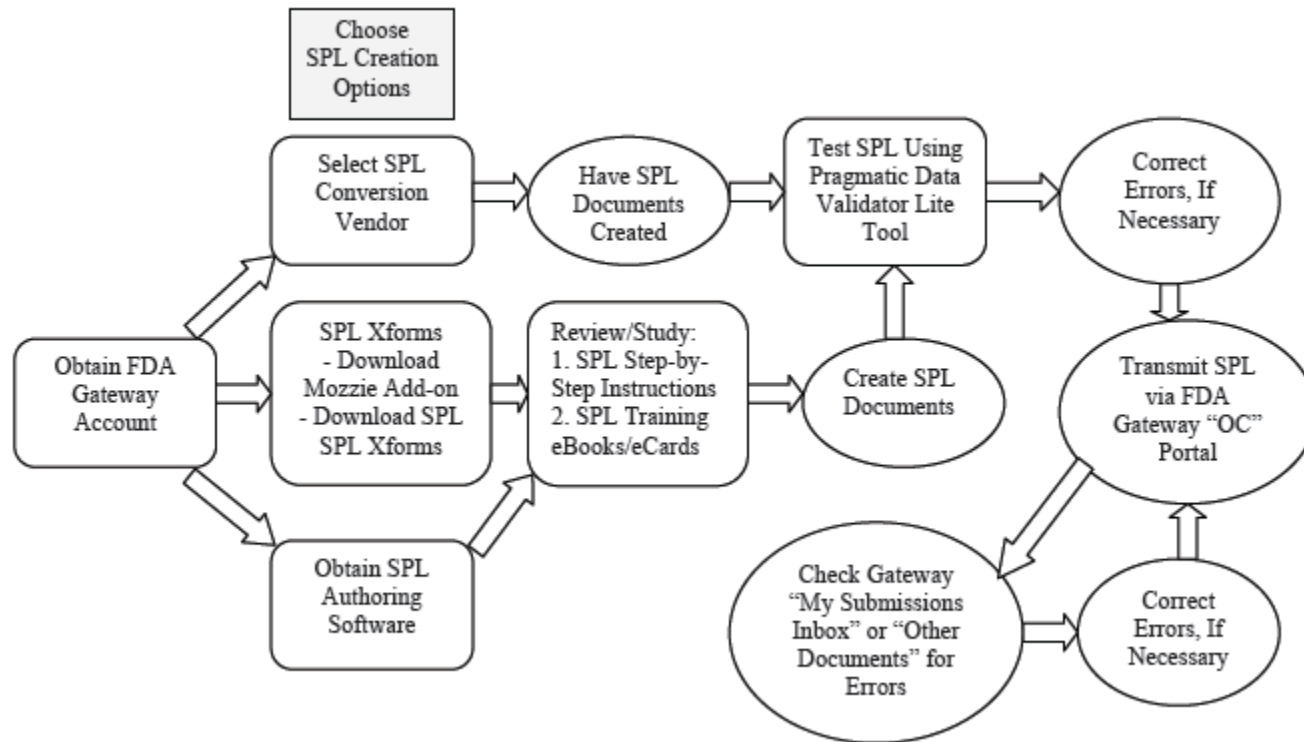


Creating a Content of Labeling/ Drug Listing SPL Document – Bulk Ingredient/Bulk Product

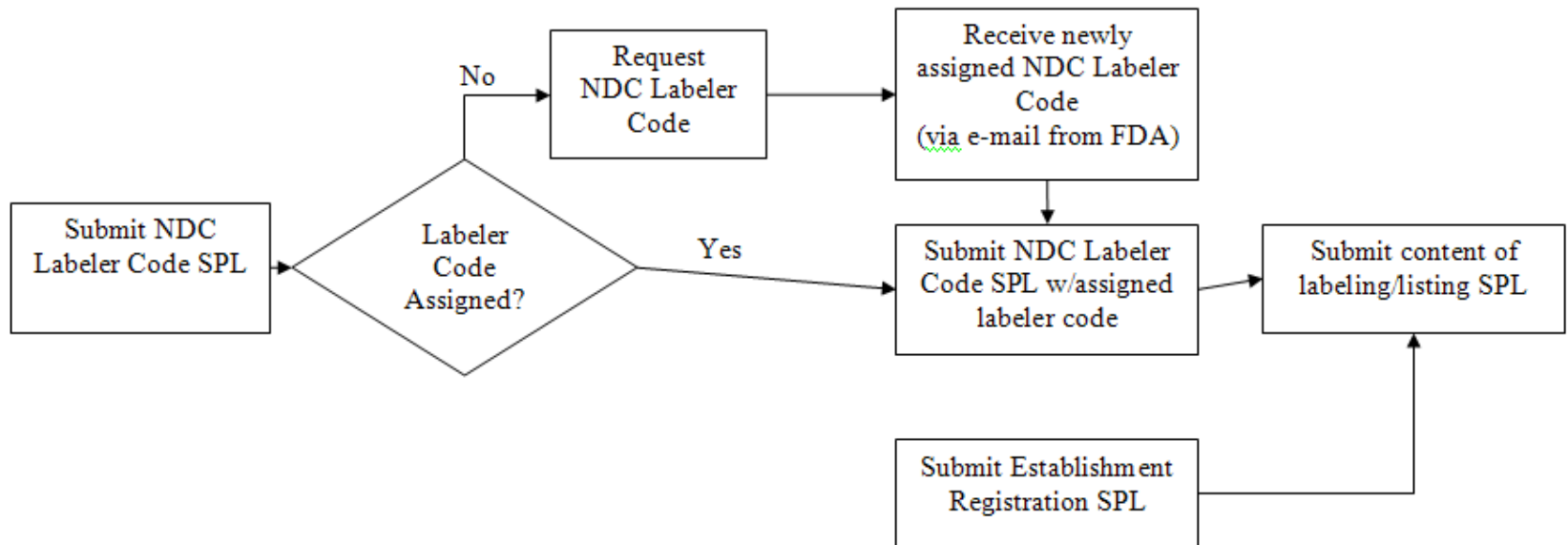
Lonnie Smith
Policy Analyst
FDA Data Standards Council



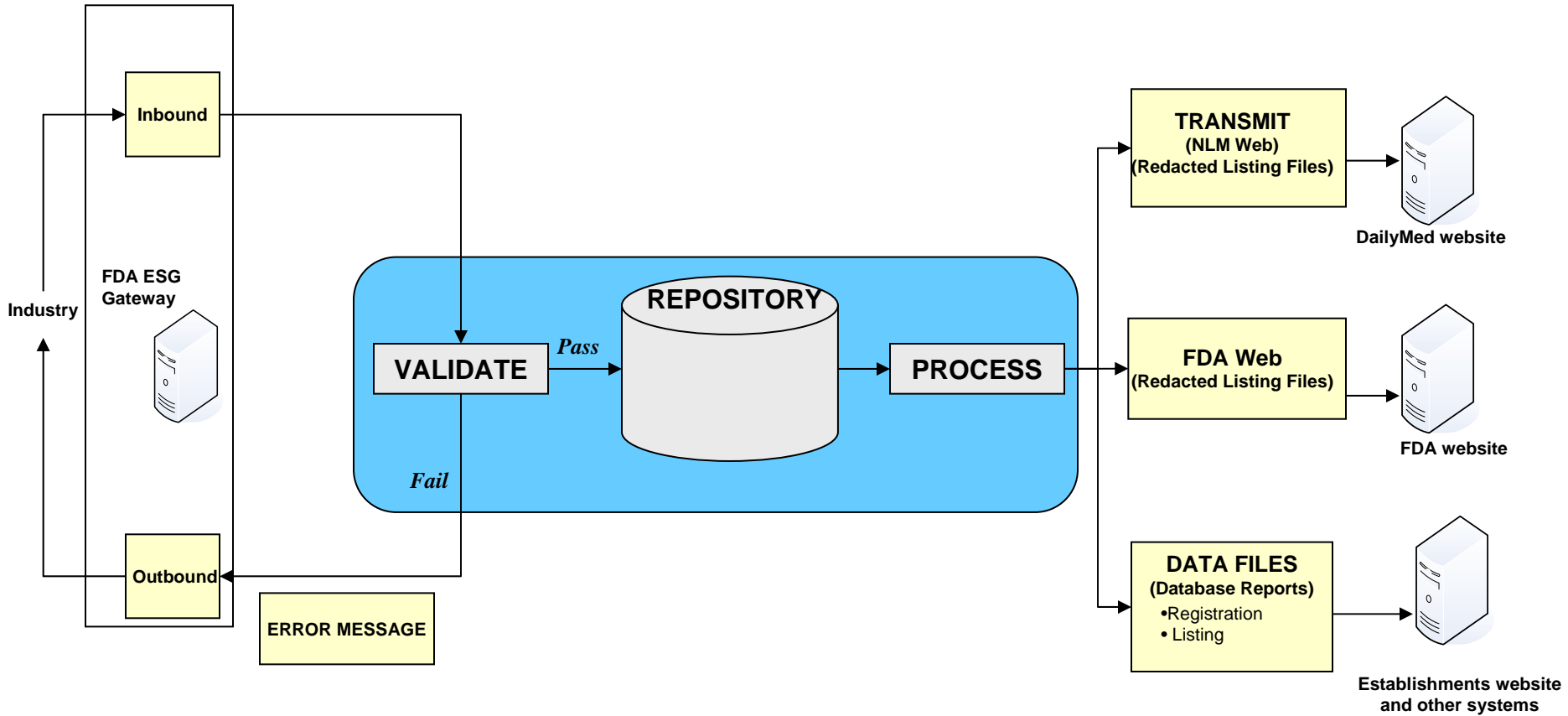
“Road Map” Creation & Submission



SPL Submission Process



eLIST



Validation Error Notifications

- Transmitted via FDA Gateway to submitter
- Transmissions occur within 36 hours (business days)
- In the form of a 2nd or 3rd acknowledgment
 - 2nd acknowledgment – system-generated message
 - 3rd acknowledgment – manually generated message with additional notes
- No 2nd or 3rd acknowledgment within 24 hours usually denotes that submission was accepted

Technical Terms Glossary

Term	Definition
Core ID	A unique identifier which the FDA ESG assigns to every submission and uses for reference purposes
Document Root ID	Globally Unique Identifier (GUID) and is unique for each version of the document. Also referred as “root ID,” “ID,” “document ID,” or “document root ID.”
Effective Time	Provides a date reference to the SPL document version or a section including the year, month and day as yyyyymmdd.
GUID	Globally Unique Identifier (used as the SPL document root ID, setID, or section IDs)
SetID	Globally Unique Identifier (GUID) and is a unique identifier for the document that remains constant through all versions/revisions of the document.
UUID	Universal Unique Identifier (UUID) Synonymous w/GUID (see definition for GUID)
Version Number	Integer greater than zero that provides a sequence to the versions of the document.


Components of API or Bulk Product Drug Listing SPL File

- Carton or container image
- Product Data Elements (drug listing)

Carton or Container

- Create a “Package.Label Principal Display Panel” section
- Include the text from the principal display panel of the carton or container label
- “Reference” image in this section

API Product Data Elements

POTASSIUM CHLORIDE			
potassium chloride powder			
Product Information			
Product Type	BULK INGREDIENT	Item Code (Source)	NDC:44444-555
Route of Administration	NOT APPLICABLE	DEA Schedule	
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Potassium Chloride (Potassium Cation)	Potassium Cation	1 kg in 1 kg	
			
Product Characteristics			
Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			
Packaging			
#	Item Code	Package Description	Multilevel Packaging
1	NDC:44444-555-12	75 kg in 1 BAG	None

Bulk Product - Product Data Elements

BENZOCAINE			
benzocaine liquid			
Product Information			
Product Type	BULK INGREDIENT	Item Code (Source)	NDC:44444-333
Route of Administration	NOT APPLICABLE	DEA Schedule	
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZOCAINE (BENZOCAINE)	BENZOCAINE	40 kg in 100 kg	
Inactive Ingredients			
Ingredient Name	Strength	Strength - Not 100%	
ALCOHOL	Inactive ingredient(s) included		
Product Characteristics			
Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			
Packaging			
#	Item Code	Package Description	Multilevel Packaging
1	NDC:44444-333-22	825 kg in 1 DRUM	None

Marketing Category – 100% API

- Select the appropriate marketing category for the API product.

Marketing Information	
Marketing Category	Application Number or Monograph Citation
Bulk ingredient	

Marketing Category – Bulk Product

- Select the appropriate marketing category for the bulk product/drug for further processing.

Marketing Information	
Marketing Category	Application Number or Monograph Citation
Drug for Further Processing	

API – Labeler/Establishment Data Elements

Labeler - Labeler Name Here (285828881)

Establishment

Name	Address	ID/FEI	Operations
Establishment 1 Name Here		222244443	API MANUFACTURE

Bulk Product-Labeler/Establishment Data Elements

Labeler - Labeler Name Here (285828881)

Establishment

Name	Address	ID/FEI	Operations
Establishment 1 Name Here		222244443	MANUFACTURE

Application or Citation Number Field

- There is no application or citation number for APIs or drugs for further processing

Marketing Status & Date

- The marketing status describes the activity of the product
- The expiration date of the last lot released to the marketplace.

Marketing Status & Dates

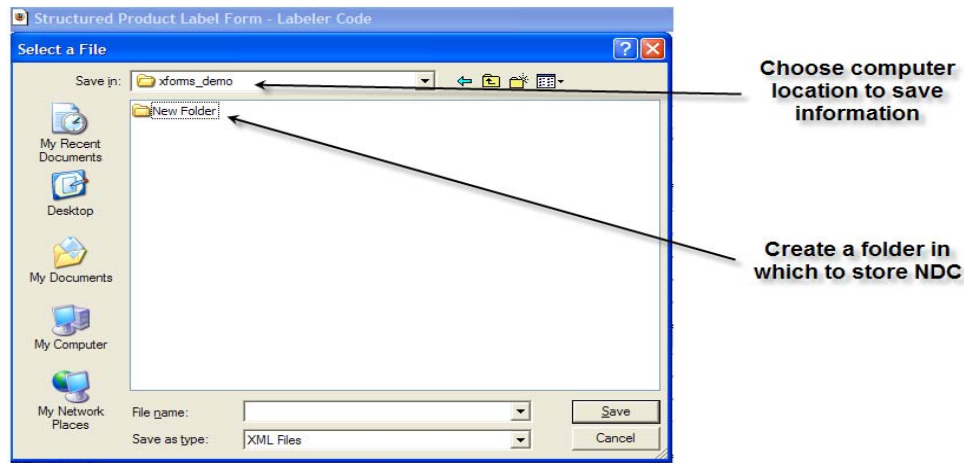
- Status of product
 - **Active:** on the market
 - **Completed:** when marketing is done the drug is no longer going to be available on the market.
 - Active or completed timestamp: effectiveTime value.
- Low value
 - Time on the market
 - Determines release of CoL/Listing SPL to public
- High value
 - Time off the market (e.g. the expiration date of the last lot released to the market.)

Marketing Start Date	Marketing End Date
01/24/2005	

Updating SPL Document Tracking Information

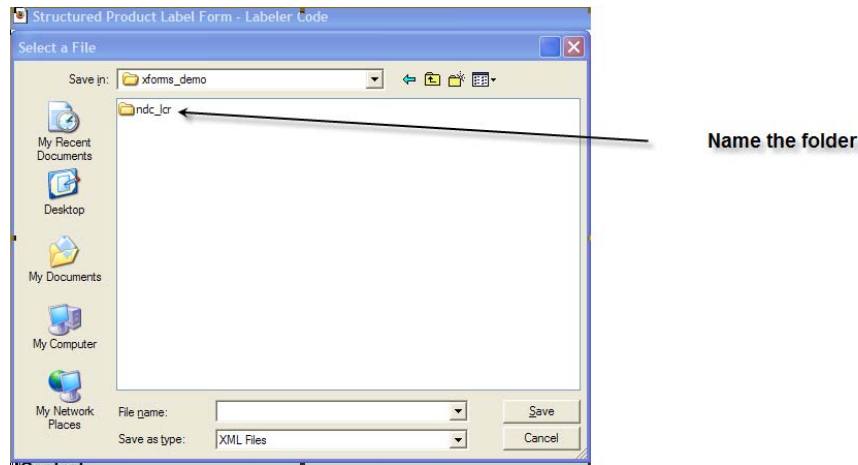
- **Use**
 - **new** id root
 - **new** version number
 - original setId
 - appropriate effective time
- **Misplaced SetID/SPL File**
 - E-mail core ID to spl@fda.hhs.gov
 - Include contact person's name and DUNS Number which were included in original SPL file

Creating the Submission Folder



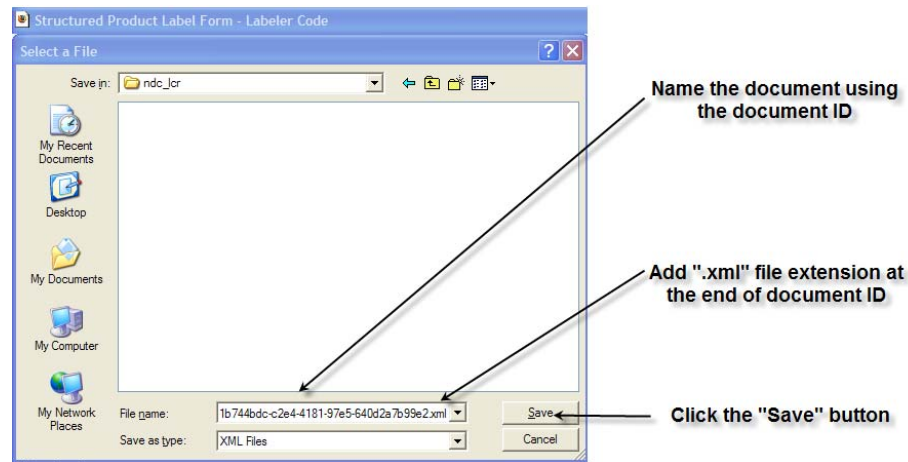
- Choose computer location in which to store folder to contain the SPL file.
- Create a folder in which to store the NDC Labeler Code SPL file.

Naming the Submission Folder



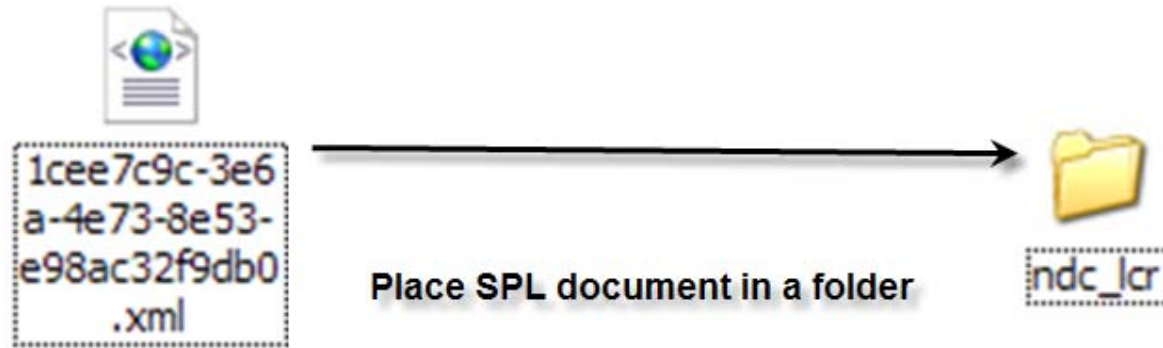
- There is no folder naming convention
- However, we recommend not using symbols in the name of the folder.

Naming the SPL File



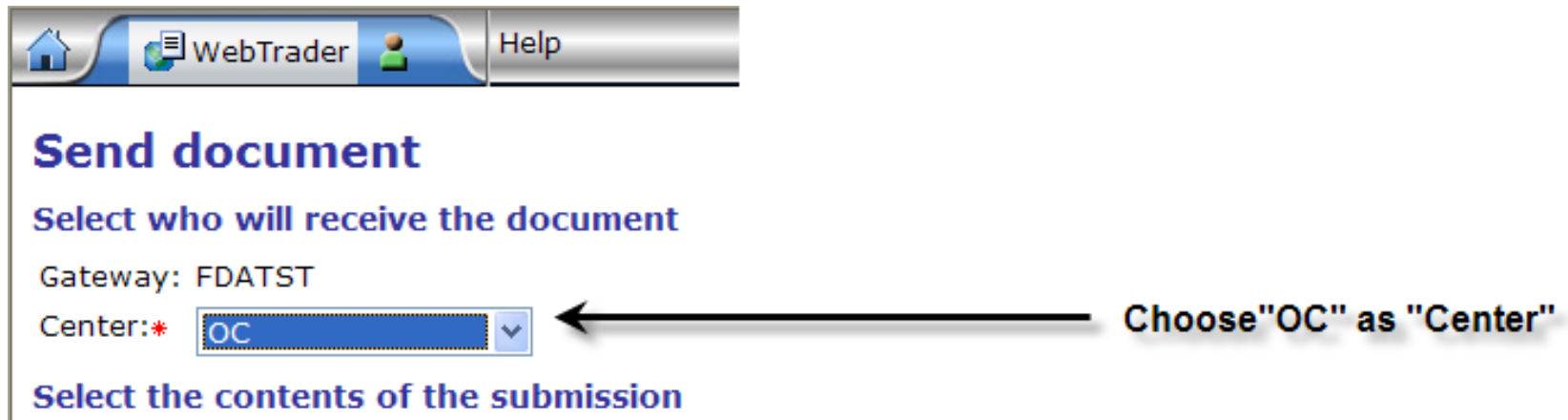
- Use the **document ID** (GUID) as the document file name
- Use “.xml” as the file extension
- Choose “Save” button
- If you do not follow these steps your SPL will **FAIL** validation.

Place SPL File in Folder



- Place SPL document in a folder.
- Ensure that SPL file name is document root ID with “.xml” as file name extension.
- Only **ONE** SPL document per folder. If applicable, image files (jpeg) may accompany listing SPL document in folder.

Choosing “Center”



WebTrader Help

Send document

Select who will receive the document

Gateway: FDATST

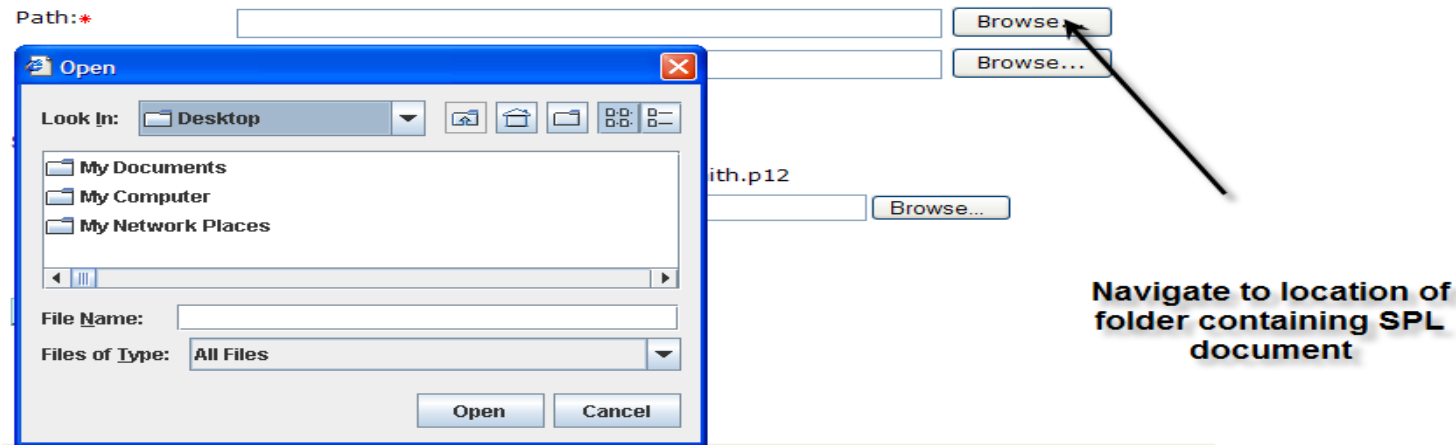
Center: * ▼

Select the contents of the submission

Choose "OC" as "Center"

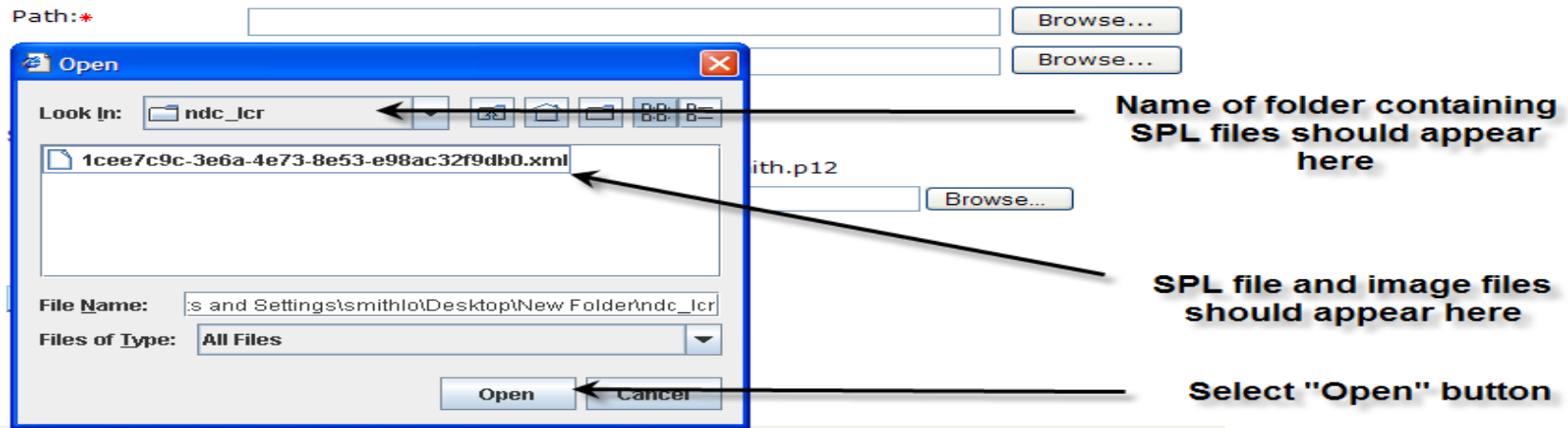
- Select “OC” as the FDA Gateway “center.”
- NDC Labeler Code, Establishment Registration, & Content of Labeling/Listing SPL documents submitted for the purpose of registering a drug establishment and listing a drug product should be sent via “OC.”

Navigate to Folder w/SPL



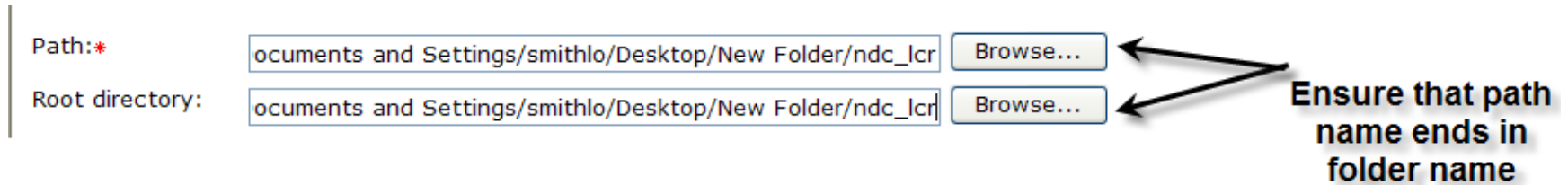
- Click browse button to navigate to location of folder containing SPL file (and, if applicable, associated image files.)

Selecting SPL Submission



- Ensure that you are sending folder.
- Check to be sure that you are not sending a folder within a folder
- Select "Open" to continue.

Checking Path Name



- Ensure that path name ends in the name of folder which contains the SPL document and JPEG files.
- If path ends in file name, then you are only sending the file and not the folder containing files.

Selecting Submission Type

Submission type: * ← **Select submission type "SPL"**

- Use drop-down menu to select submission type “SPL.”
- If submission type “SPL” does not appear, you have chosen the wrong center and not “OC.”

Verify or Select Digital Certificate



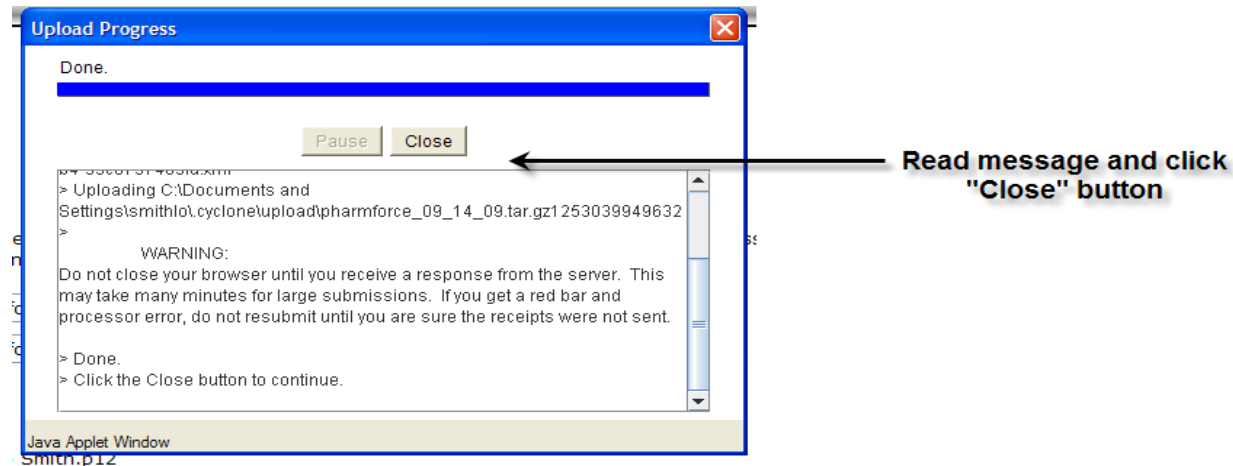
- Verify that your digital certificate is being used.
- Or browse to the location of the digital certificate on your computer.

Sending the Submission



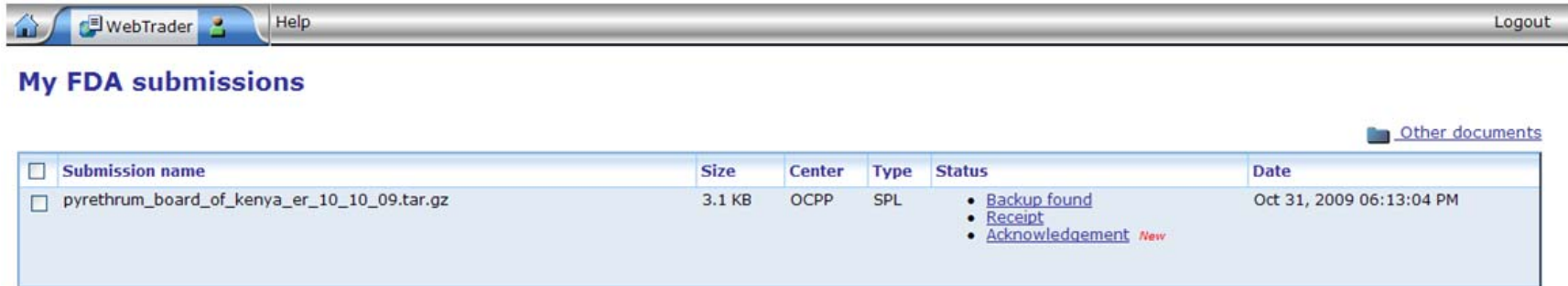
- Select the “Send” button.
- Enter your password to unlock signing certificate.
- Select the “OK” button

Completing Gateway Submission



- Read message in prompt window
- Select "Close" button

Log onto FDA Gateway




The screenshot shows the FDA Gateway WebTrader interface. At the top is a navigation bar with a home icon, 'WebTrader', a user icon, 'Help', and a 'Logout' link. Below this is a section titled 'My FDA submissions'. To the right of this section is a link for 'Other documents'. The main content is a table with columns: Submission name, Size, Center, Type, Status, and Date. A single submission is listed: 'pyrethrum_board_of_kenya_er_10_10_09.tar.gz' with a size of 3.1 KB, center OCPP, and type SPL. The status column contains a bulleted list of links: 'Backup found', 'Receipt', and 'Acknowledgement' (marked as 'New'). The date is 'Oct 31, 2009 06:13:04 PM'.

<input type="checkbox"/>	Submission name	Size	Center	Type	Status	Date
<input type="checkbox"/>	pyrethrum_board_of_kenya_er_10_10_09.tar.gz	3.1 KB	OCPP	SPL	<ul style="list-style-type: none">• Backup found• Receipt• Acknowledgement <i>New</i>	Oct 31, 2009 06:13:04 PM

- Log onto the FDA Gateway
- Select the “My FDA submissions” or “Other documents” hyperlinks

Selecting the File w/Core ID

Center	Type	Status	Date
OCPP	SPL	<ul style="list-style-type: none">• Backup found• Receipt• Acknowledgement <i>New</i>	Oct 31, 2009 06:13:04 PM



Click the "Acknowledgment" hyperlink

- The **first** "Acknowledgment" link should take you to window with core ID.

Finding the Core ID

The screenshot shows a table with columns: Size, Center, Type, Status, and Date. The first row is highlighted with a blue background. Below the table, an 'Acknowledgment' window is open, displaying email details. An arrow points to the Core ID in the top left of this window.

Size	Center	Type	Status	Date
3.1 KB	OCPP	SPL	<ul style="list-style-type: none">Backup foundReceipt	Oct 31, 2009 06:13:04 PM

close

ci1257027185381.4044@lntap02_te.txt

From: [FDATST](#)

To: [Lonnie Smith \(FDA\)](#)

Date: Oct 31, 2009 06:16:03 PM EDT

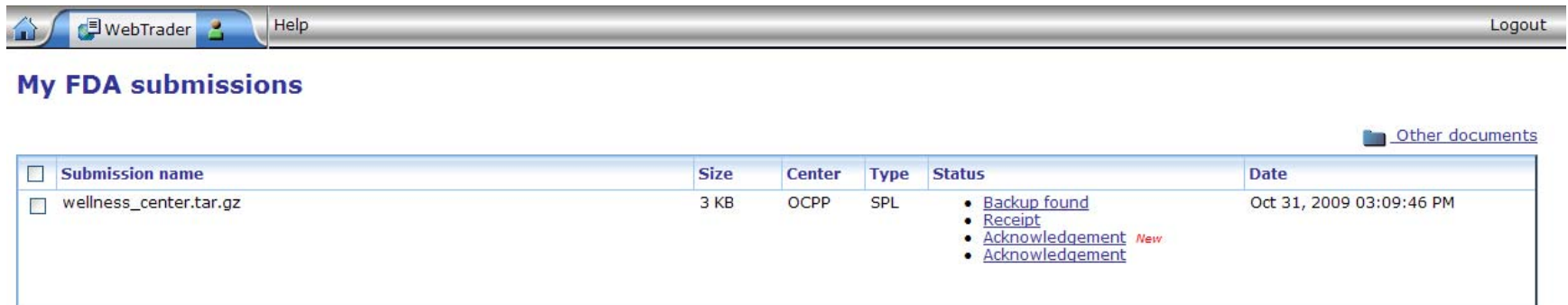
Submission messageID: <7346727.1257027182095.JavaMail.smithlo@cdl0080685>

[View document](#)

This is the core ID

- After selecting the “Acknowledgment” hyperlink, window should display.
- Core ID is located in top left of “Acknowledgment” window. (.txt is not part of the actual core ID)
- Use this core ID to reference submission when communicating with FDA about status or issue with SPL document.

Finding Error Messages



The screenshot shows the FDA Gateway WebTrader interface. At the top is a navigation bar with a home icon, 'WebTrader', a user icon, 'Help', and a 'Logout' link. Below the bar is the heading 'My FDA submissions'. To the right of this heading is a link for 'Other documents'. Below is a table with columns: Submission name, Size, Center, Type, Status, and Date. One submission is listed: 'wellness_center.tar.gz' (3 KB, OCPP, SPL). The Status column for this submission contains a bulleted list of links: 'Backup found', 'Receipt', 'Acknowledgement' (marked as 'New'), and another 'Acknowledgement'.

<input type="checkbox"/>	Submission name	Size	Center	Type	Status	Date
<input type="checkbox"/>	wellness_center.tar.gz	3 KB	OCPP	SPL	<ul style="list-style-type: none">• Backup found• Receipt• Acknowledgement <i>New</i>• Acknowledgement	Oct 31, 2009 03:09:46 PM

- Logon to the FDA Gateway
- Select the “My FDA submissions” or “Other Documents” hyperlinks

Selecting Error Message

Size	Center	Type	Status	Date
3 KB	OCPP	SPL	<ul style="list-style-type: none">• Backup found• Receipt• Acknowledgement• Acknowledgement New	Oct 31, 2009 03:09:46 PM



Click on second (or third) "Acknowledgment" hyperlink

- Receipt of a second or third “Acknowledgment” hyperlink is indicative that there is an error with your submission.
- Click on second (and third, if available) “Acknowledgment” hyperlink.

Opening Error Messages

The screenshot shows a web interface with a table of messages and a detailed view of a selected message. The table has columns: Size, Center, Type, Status, and Date. The first row is highlighted and shows a 3 KB message from OCPP, Type SPL, Status with links for Backup found, Receipt, and Acknowledgement (marked as New), and Date Oct 31, 2009 03:09:46 PM. Below the table, a detailed view of the selected message is shown, including the filename ci1257016187076.9279@lntap01_te.xml, From: F0ATST, To: Lonnie Smith (FDA), Date: Nov 1, 2009 12:34:11 PM EST, and Submission messageID: <18012736.1257016184535.JavaMail.smithlo@cdl0080685>. A 'View document' hyperlink is at the bottom left of the detailed view, with an arrow pointing to it and a caption 'Click "View document" hyperlink'.

Size	Center	Type	Status	Date
3 KB	OCPP	SPL	<ul style="list-style-type: none">Backup foundReceiptAcknowledgement <i>New</i>	Oct 31, 2009 03:09:46 PM

[close](#)

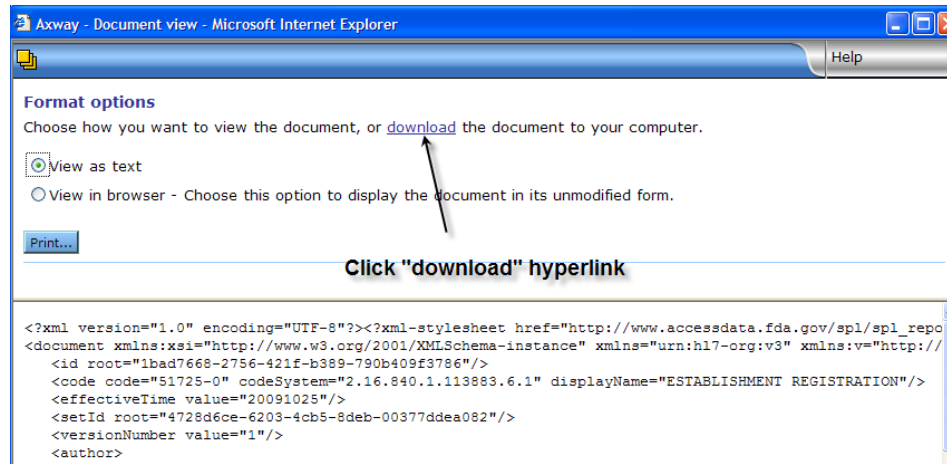
ci1257016187076.9279@lntap01_te.xml

From: [F0ATST](#)
To: [Lonnie Smith \(FDA\)](#)
Date: Nov 1, 2009 12:34:11 PM EST
Submission messageID: <18012736.1257016184535.JavaMail.smithlo@cdl0080685>
[View document](#)

Click "View document" hyperlink

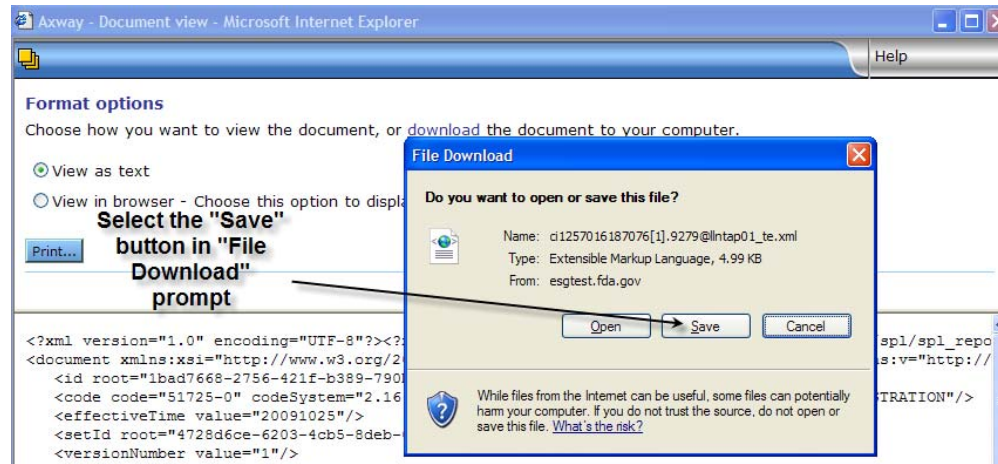
- Click the “View Document” located in the bottom left corner of Acknowledgment prompt window.

Downloading Error Message



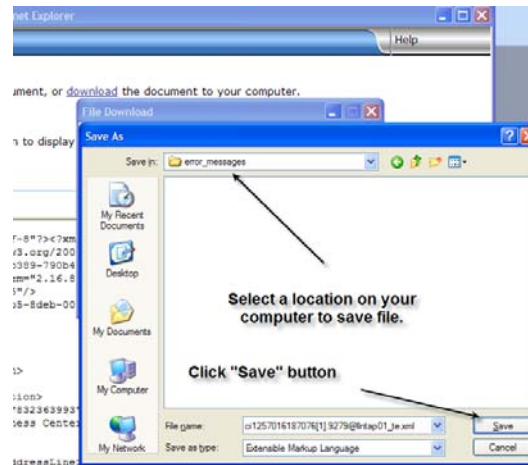
- Select the “download” hyperlink to download the error message to location on computer

Saving the Error Message Document



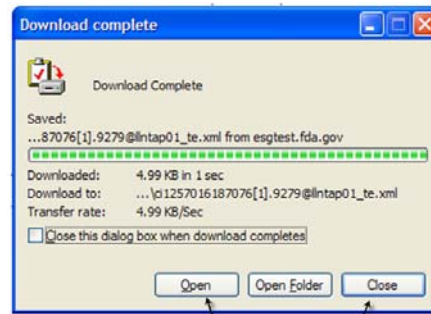
- Click the “Save” button in the “File Download” window prompt.

Saving the Error Message Document cont...



- Navigate to preferred location on your computer in which to store the error message.
- Click the “Save” button to save message in preferred location.

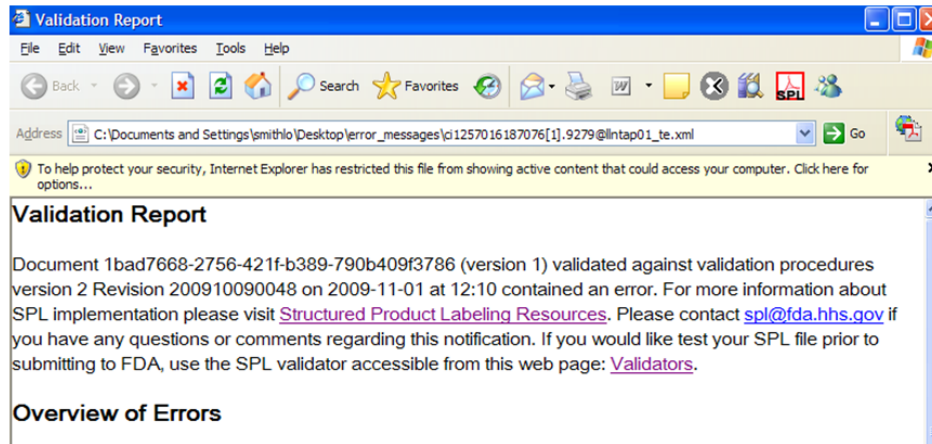
Completing Download



Select "Open" or "Close" buttons

- You can open the message from the "Download complete" window prompt
- You can also close the window and directly open from location on your computer where message was stored.

Review the Error Message



- Review the error message

Configuring PC to View Error Message

- If you are experiencing technical difficulties resulting in your inability to view the error message you have downloaded, we recommend that you follow these steps for Internet Explorer
 - Click the "Tools" menu and select "Internet Options".
 - Click the "Security" tab.
 - Click the "Custom level" button.
 - Scroll down to the "Miscellaneous" section.
 - Enable the "Access data sources across domains".
 - Click "OK" to accept the update.
 - Click "OK" to close the security dialog.

Test Your SPL R4 Submissions

- Use Pragmatic Data Validator Lite to test your SPL files prior to transmission to FDA:
<http://www.fda.gov/ForIndustry/DataStandards/ucm155514.htm>
- NOTE
 - This validator tool is **NOT** connected to FDA database.
 - This tool assist you in detection of **90 – 95%** of technical errors in SPL documents.

Stay Informed

- Join FDA Data Standards Council listserv
- <http://www.fda.gov/ForIndustry/DataStandards/default.htm>



The screenshot shows the FDA Data Standards Council website. At the top is the U.S. Department of Health & Human Services header with the www.hhs.gov URL. Below this is the FDA U.S. Food and Drug Administration logo and a search bar. A navigation bar lists various FDA categories: Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. The 'For Industry' section is highlighted, with a breadcrumb trail: Home > For Industry > Data Standards. On the left is a 'Data Standards' sidebar menu with links to Validators, Data Council, Structured Product Labeling, Individual Case Safety Reports, and Regulated Product Submission. The main content area is titled 'FDA Resources for Standards' and features a 'Sign up for email updates.' link with an arrow pointing to it. Below this is a paragraph explaining the council's role in coordinating data standards. At the bottom of the main content area is a link for 'Structured Product Labeling'.

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration

A-Z Index Search go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

For Industry Email this page Print this page Change Font Size

Home > For Industry > Data Standards

Data Standards

- Validators
- Data Council
- Structured Product Labeling
- Individual Case Safety Reports
- Regulated Product Submission

FDA Resources for Standards

 Sign up for email updates. ←

The FDA Data Standards Council coordinates the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency.

[Structured Product Labeling](#)

SPL-related Technical Assistance/Questions

- SPL e-mail account (spl@fda.hhs.gov)

QUESTIONS?